UNITED STATES
PATENT AND
TRADEMARK OFFICE

UNDER SECRETARY OF COMMERCE FOR INTELLECTUAL PROPERTY AND
DIRECTOR OF THE UNITED STATES PATENT AND TRADEMARK OFFICE
WASHINGTON, D.C. 20231
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OCT 15 2002

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In re Application of	:	
PELLETIER et al.	:	
Serial No.: 09/407,804	:	DECISION ON PETITION
Filed: 28 September 1999	:	
Attorney Case No. 073406-0402	:	

This is in response to the Petition filed 8 July 2002, for review of the restriction requirement set forth on 4 August 2001 as Paper No. 15 in the above-identified application. Although the Petition was filed under the provisions of 37 CFR 1.181, it is being considered under the provisions of 37 CFR 1.144. 37 CFR 1.144 sets forth that any final requirement for restriction is subject to review on petition to the Commissioner. The Commissioner has delegated any first review of an examiner's final restriction requirement to the Group Director.

BACKGROUND

A review of the file shows that this application was filed under 35 USC 111(a) on 28 September 1999 and claims benefit to under 35 USC 119(e) to provisional application 60/110,992, filed 3 December 1998.

The issue under petition is the Restriction Requirement as set forth in Paper No. 15.

In Paper No. 15, mailed 4 August 2001, the examiner set forth the following restriction requirement under 35 U.S.C. 121:

I *Claims 9, 10 and 12-4[1], drawn to various isolated, purified or enriched nucleic acid sequences and recombinant vectors and cells comprising a bacteriophage 77 open reading frame 17, 19, 43, 102, 104 or 182, which are SEQ ID Nos. 4, 5, 6, 7, 8 and 9, respectively, classified in class 536, subclass 23.1.*

II. *Claim 11, drawn to an isolated purified or enriched polypeptide encoded by the bacteriophage 77 open reading frame 17, 19, 43, 102, 104 or 182, classified in class 530, subclass 300+.*

Both groups I and II recite six different open reading frames. Where Group I or II is elected, applicant is also required to elect one of the SEQ ID Nos 4, 5, 6, 7, 8, or 9 because each is a different polynucleotide in Group I and each is a different polypeptide in Group II.

Note that claims 1-8 and 15-32 had been canceled and that claims 33-72 were already withdrawn from examination due a previous Restriction Requirement, which is not under review in this petition.

In Paper No. 18 filed 10 January 2002, Applicants elected Group I and SEQ ID No. 8, corresponding to open reading frame 104, with traverse. The traverse was on the grounds that the election of a single sequence is inappropriate because MPEP 803.04 and the Official Gazette Notice dated 17 October 1996, entitled "Examination of Patent Applications Containing Nucleotide Sequences," requires examination in most cases of up to 10 independent and distinct sequences. Applicants requested examination of polynucleotides SEQ ID Nos. 4-9 in Group I and examination of the polypeptides encoded by SEQ ID Nos. 4-9 in Group II.

On 8 April 2002, in Office action Paper No. 19, the examiner acknowledged the election of Group I, claim 9 (in part) and claims 10, 12-14 with respect to SEQ ID No. 8. The examiner considered the traversal but found it not persuasive. The Examiner reasoned that each polynucleotide sequence and each polypeptide sequence is patentably distinct. Concerning the request for rejoinder of Group II with Group I, the arguments were not found persuasive because the inventions require more than the search of the DNA or amino acid databases. Literature searches are also required and would be more burdensome in addition to the required search to the different patent classes and subclasses. The DNA and protein have different modes of operation and are structurally, functionally, patentably distinct. The DNA and protein are unrelated because they are not capable of being used together. The Restriction Requirement was made Final.

Claims 11, 33-36, 38, 40-43, 45 and 48-70 were withdrawn under 37 CFR 1.142(b) from further consideration as being directed to the non-elected invention. Claims 9, 10, 12-

[1] This should have stated Claims 9, 10 and 12-14.

14, 37, 39, 44, 46, 47, 71 and 72 were examined to the extent that they read upon SEQ ID No. 8. Claims 9, 10, 12-14, 37, 39, 44, 46, 71 and 72 were rejected under 35 U.S.C. 112 first paragraph for lacking the full scope of enablement. Claims 9, 12 and 13 and dependent claims were rejected under 35 U.S.C. 112, second paragraph for indefiniteness. Claims 9, 10 and 39 were rejected under 35 U.S.C. 102(b) as being anticipated by Black et al.

On 8 July 2002, as Paper No. 21, Applicants filed a Petition under the provisions of 37 CFR 1.181 to compel the Group Director of TC1600 to comply with the Notice provided in 1192 O.G. 68 allowing up to ten independent sequences to be claimed in one application.

On 21 August 2002, the Office of Petitions considered and dismissed as premature the Petition filed 8 July 2002. The dismissal letter explained that 37 CFR 1.144 sets forth that any final requirement for restriction is subject to review on petition to the Commissioner. The Commissioner has delegated any first review of an examiner's final restriction requirement to the Group Director.

The Petition now being treated as a Petition filed under 37 CFR 1.144.

In the Petition filed 8 July 2002, Applicants again argue that the O.G. Notice requires an examination of up to ten sequences in most cases and that requiring applicants to elect one sequence places a financial burden on applicants to file additional applications.

DISCUSSION

The file record, the restriction requirement and petition have been carefully considered.

Applicants have requested that the restriction requirement concerning the election of one sequence be withdrawn in view of the 1192 OG Notice published October 17, 1996 (1192 OG 68) and MPEP 803.04.

The petition states that any per se rule requiring only one sequence to be examined in a particular application would place an enormous burden on applicants, hinder protection for their inventions and have a deleterious affect on the biotechnology industry. The petition argues that the examiner has superseded the Commissioner's considered opinions and policy expressed in the OG Notice.

These arguments have been considered carefully and found not to be persuasive for the following reasons. Applicants are correct that the Official Gazette Notice is directed to the examination of patent applications containing distinct nucleotide sequences. The OG Notice and MPEP 2434 are silent concerning the examination of multiple polypeptide sequences and cannot support a request for examination of 10 polypeptides in Group II.

Turning now to the Inventions listed in Group I, according to 35 USC 121, the examiner can require applicant to elect a single invention. In the biotechnology arts, sometimes a single invention encompasses only one molecule comprising a polynucleotide sequence.

The examination of the elected DNA sequence SEQ ID No.8 would not solely require a search of nucleic acid databases, but would also require a search of other, non-sequence databases and patent and non-patent references. As to the question of burden of search, the literature search, particularly relevant in this art, is not co-extensive and is also important in evaluating the burden of search. Clearly different searches and different issues are involved in the examination of each invention. In order to examine more than one of the DNA sequences, as claimed, the Office would be required to search additional DNA sequences, on patent and non-patent literature, and on a variety of sequence databases.

The Official Gazette Notice and MPEP 803.04 do not require examination of ten polynucleotide sequences in one application. The OG Notice and MPEP 803.04 permit the examiner to examine up to ten polynucleotide sequences in one application. According to 35 USC 121, the examiner can require applicant to elect a single invention. A restriction of one sequence is consistent with both the requirements of the OG Notice, MPEP 803.04 and 35 U.S.C. 121. One sequence falls within the range of "up to ten" permitted by the Official Gazette Notice. The restriction requirement between the various polynucleotide molecules, between the various polypeptides and between the DNA and encoded polypeptide was proper.

MPEP 2434 also states that should applicant traverse on the ground that the sequences are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the sequences unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other sequence.

DECISION

Applicants' petition is **DENIED** for the reasons set forth above.

Since no fee is required for the filing of this petition, Applicants' Deposit Account 50-0872 will be credited the $130.00 petition fee.

Applicants remain under obligation to properly respond to the Office Action mailed 3 April 2002, within the time period set therein or as extendable under the provisions of 37 CFR 1.136(a).

Any request for reconsideration of this decision must be by way of a renewed petition and must be filed within TWO MONTHS of the date of mailing of this decision in order to be considered timely.

Should there be any questions with respect to this decision, please contact Special Program Examiner Julie Burke, Ph.D. by letter addressed to the Director, Technology Center 1600, Washington DC 20231. Alternatively, SPRE Burke can be reached by telephone at (703) 308-7553 or by facsimile transmission at (703) 305-7230.

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